

From: e-Pharm/alert <[epharmalert@alertmarketingmail.com](mailto:epharmalert@alertmarketingmail.com)>

Date: February 12, 2014 at 9:40:14 AM EST

To:

Subject: e-Pharm/alert: All fenofibrates are not created equal

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**Lipofen® 50 mg & 150 mg**  
(fenofibrate capsules, USP)



**THERE IS NO GENERIC  
EQUIVALENT OF LIPOFEN®**

When a patient is prescribed LIPOFEN® (fenofibrate capsules, USP), a generic fenofibrate may not be the best option. Only LIPOFEN offers Lidose® technology, which:

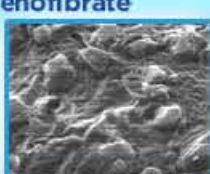
- Uses a unique lipid melt matrix system not available with any other generic or brand-name fenofibrate<sup>2,4</sup>
- Delivers reliable, consistent, and uniform delivery<sup>2,3</sup>
- Avoids dependence on particle formulation<sup>2</sup>
- May improve the safety and efficacy of the active ingredient in LIPOFEN by offering more consistent plasma profiles<sup>3</sup>

#### LIPOFEN Takes Particle Size Out of the Equation<sup>4</sup>

##### Ordinary Fenofibrate



Mapping Cl-\*



ESEM†

##### LIPOFEN With Lidose



Mapping Cl-\*



ESEM†

\*Chloride anion.

†Environmental scanning electron microscopy.

- Other fenofibrates are formulated with small particles, which may affect absorption<sup>3</sup>  
— With LIPOFEN, particle size is not an issue<sup>4</sup>
- Fenofibrate is in an already-dissolved state, making it readily available for absorption<sup>4</sup>
- LIPOFEN with Lidose technology offers a very homogeneous distribution of fenofibrate in the mass of excipients<sup>3</sup>  
— No crystals of fenofibrate are observed<sup>3</sup>

### Indications and Important Safety Information about LIPOFEN® (fenofibrate capsules, USP)

#### INDICATIONS<sup>5</sup> for LIPOFEN®

- LIPOFEN is indicated as adjunctive therapy to diet to reduce elevated low-density lipoprotein cholesterol (LDL-C), Total Cholesterol (Total-C), Triglycerides (TG), and apolipoprotein B (Apo B), and to increase high-density lipoprotein cholesterol (HDL-C) in adult patients with primary hypercholesterolemia or mixed dyslipidemia.
- LIPOFEN is also indicated as adjunctive therapy to diet for treatment of adult patients with severe hypertriglyceridemia.
- Improving glycemic control in diabetic patients showing fasting chylomicronemia will usually obviate the need for pharmacologic intervention.
- Markedly elevated levels of serum triglycerides (e.g. > 2,000 mg/dL) may increase the risk of developing pancreatitis. The effect of fenofibrate therapy on reducing this risk has not been adequately studied.

#### IMPORTANT LIMITATIONS OF USE

- Fenofibrate at a dose equivalent to 150 mg of LIPOFEN was not shown to reduce coronary heart disease morbidity and mortality in two large, randomized controlled trials of patients with type 2 diabetes mellitus.

#### IMPORTANT SAFETY INFORMATION<sup>5</sup> FOR LIPOFEN®

##### CONTRAINDICATIONS

- Patients with severe renal impairment, including those receiving dialysis.
- Patients with active liver disease, including those with primary biliary cirrhosis and unexplained persistent liver function abnormalities.
- Patients with preexisting gallbladder disease.
- Patients with known hypersensitivity to fenofibrate or fenofibric acid.
- Nursing mothers.

##### WARNINGS AND PRECAUTIONS

- **Coronary Heart Disease Morbidity and Mortality:** The effect of LIPOFEN on coronary heart disease morbidity and mortality and non-cardiovascular mortality has not been established.
- **Skeletal Muscle:** Fibrates increase the risk of myopathy, and rhabdomyolysis has been reported in patients taking fibrates; rhabdomyolysis risk is increased in the elderly, patients with diabetes, renal insufficiency or hypothyroidism. Patients should be advised to promptly report unexplained muscle pain, tenderness or weakness. LIPOFEN should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed.
- **Liver Function:** Fenofibrate can increase serum transaminases. Baseline and regular monitoring of liver tests, including ALT should be performed for the duration of therapy with LIPOFEN, and therapy discontinued if enzyme levels persist above three times the normal limit.
- **Serum Creatinine:** LIPOFEN can reversibly increase serum creatinine levels. Renal monitoring should be considered for patients with renal impairment and also for any patients at risk for renal insufficiency, i.e. the elderly and those with diabetes.
- **Cholelithiasis:** Fenofibrate, like clofibrate and gemfibrozil, may increase cholesterol excretion into the bile, leading to cholelithiasis. If cholelithiasis is suspected, gallbladder studies are indicated. LIPOFEN therapy should be discontinued if gallstones are found to be present.
- **Coumarin Anticoagulants:** Exercise caution in concomitant treatment with coumarin anticoagulants. Dose adjustment of these anticoagulants may be needed to maintain the Prothrombin Time/International Normalized Ratio (PT/INR) at the desired level to prevent bleeding complications. Frequent monitoring of PT/INR and dose adjustment of anticoagulants is recommended until the PT/INR has stabilized.
- **Other Precautions:** Pancreatitis, hematologic changes, hypersensitivity reactions, venothromboembolic disease, and paradoxical decreases in HDL cholesterol levels have been observed in patients taking fenofibrate.

##### ADVERSE EVENTS

In clinical trials, the most common adverse events reported by 2% or more of patients and greater than placebo were:  
Abdominal Pain, Back Pain, Headache, Abnormal Liver Function Tests, Nausea, Constipation, Increased ALT, Increased AST and Increased CPK, Respiratory Disorder and Rhinitis.

##### DRUG INTERACTIONS

Drug interactions have been observed with fenofibrate.

- **Coumarin Anticoagulants**, please see the prescribing information for additional information to that given above.
- **Immunosuppressants** may place patients at risk of deterioration to their renal function. Kidney function should be monitored.
- **Bile-Acid Binding Resins** may affect fenofibrate absorption. Prescribe fenofibrate doses at least 1 hour before or 4–6 hours after the resin dose.
- **Colchicine** co-administered with fenofibrate should be done with caution and monitor closely for myopathy, including rhabdomyolysis.

For additional information please see the full Prescribing Information available at [www.LipofenRx.com](http://www.LipofenRx.com)

LIP-RA-0022 V-1/2013r

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LIPOFEN is a registered trademark of Cipher Pharmaceuticals Inc. and licensed by Kowa Pharmaceuticals America, Inc.

References: 1. Food and Drug Administration. Orange book: approved drug products with therapeutic equivalence evaluations. FDA Web site. <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>. Accessed May 7, 2013. 2. Food and Drug Administration Web site—Cipher Pharmaceuticals Limited. Fenofibrate capsules 50 mg, 100 mg, 150 mg, and 160 mg: Notice of paragraph IV patent certification pursuant to 21 U.S.C. § 355(b)(3)(B) and 21 C.F.R. § 314.52. Available at: <http://www.fda.gov/ohrt/dockets/dockets/04p0386/04p-0386-cp00001-Exhibit-04-French-vol1.pdf>. Accessed May 7, 2013. 3. Laboratoires S.M.B. Web site. Lidose. <http://www.smlab.be/index.php/formulation/lidose>. Accessed May 7, 2013. 4. United States Patent and Trademark Office Web site. Pharmaceutical composition containing fenofibrate—Patent 5,545,628. Available at: <http://patft.uspto.gov>. Accessed May 7, 2013. 5. LIPOFEN [prescribing information]. Montgomery, AL: Kowa Pharmaceuticals America, Inc; January 2013.

**Please see full Prescribing  
Information for LIPOFEN  
Capsules.<sup>5</sup>**



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